

**REMARKS**

The Office Action mailed September 6, 2007 has been carefully considered and the following is responsive thereto.

Claim 1 has been amended to add that the alginate is at least one of propylene glycol alginate or salts of said alginate and combinations thereof. Support for the amendment to claim 1 can be found throughout the specification and in particular in original claim 4. Claims 3 and 4 have been canceled without prejudice. Claims 7 and 17 have been amended.

**Rejection under 35 USC 112, second paragraph**

At page 2 of the Office Action, the Examiner rejected claim 17 as indefinite. The Examiner alleged that there is insufficient antecedent basis for the limitation, "said polyvalent cation" in the second last line of the claim.

Applicants traverse this rejection. Claim 17 has been amended to delete "said polyvalent cation is at least one member selected from the group consisting of calcium, magnesium, aluminum and chromium." Withdrawal of this section 112, second paragraph rejection is respectfully requested.

**Rejection under 35 USC 103**

Claims 1-22, 29-34 and 36-38 were rejected under 35 USC 103 as unpatentable over Gilleland et al. (U.S. Patent 6,375,981) in view of Colegrove (U.S. Patent 6,509,311). The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition comprising alginate as the gum, starch, and plasticizer for soft gel films and gelatin replacement capsules and assess the thermoreversibility of the films, as suggested by Gilleland, and combine it with the propylene glycol alginates, as suggested by Colegrove, and produce the instant invention.

Applicants traverse this rejection.

Claim 1 as presently amended is directed to a homogeneous, thermoreversible gel film comprising a film forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent,

wherein the alginate is at least one of propylene glycol alginate or salts of said alginate and combinations thereof. Claims 2, 5-35 and 38 (in part) depend directly or indirectly from claim 1. Claim 36 is directed to a homogeneous, thermoreversible gel film consisting of a film forming amount of a water soluble thermoreversible alginate, flavorant and water. Claims 37 and 38 (in part) depend from claim 36.

Gilleland discloses the use of modified starch as a replacement for gelatin in soft gel films and capsules. The film forming compositions of Gilleland et al. comprise modified or waxy starch, gum and plasticizers. Alginates are mentioned as one example of a preferred gum. Gilleland does not disclose the use of propylene glycol alginate.

Colegrove discloses a gel system comprising propylene glycol alginate and an aluminum salt. The gels are disclosed as useful for personal care formulations such as a room deodorant gel.

Claims 1-2, 5-22, 29, 34 and 36-38 are not obvious over Gilleland et al. in view of Colegrove et al. The Examiner has not explained where in Colegrove et al. one skilled in the art would find suggestion that the propylene glycol alginate used in the gels disclosed therein for personal care formulations could also be used in the homogeneous, thermoreversible gel films of the present invention that are useful, for example, in the preparation of soft capsules. Applicants respectfully submit that persons skilled in the art would not be motivated to use the propylene glycol alginate disclosed in Cade et al. in the soft gel films and capsules of Gilleland et al. As explained in the present application, for example, at page 7, last paragraph, certain alginates, such as propylene glycol alginate, are generally considered to be non-gelling. To the Applicants surprise, however, propylene glycol alginate provides a homogeneous, thermoreversible gel film having significant film strength.

Claims 1-2, 5-22, 29-34 and 36-38 are not obvious in view of Gilleland et al. and Colegrove et al. Withdrawal of this section 103 rejection is respectfully requested.

### **Rejection under 35 USC 103**

At page 9 of the Office Action, the Examiner rejected claim 35 under 35 USC 103 as being unpatentable over Gilleland et al. (U.S. Patent 6,375,981) in view of Cade et al. (U.S.

Patent 6,517,865). The Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film forming thermoreversible composition comprising alginate as the gum, as suggested by Gilleland, and combine it with the composition without plasticizer, as suggested by Cade et al. and produce the instant invention. The rationale for the combination asserted by the Examiner was that Cade et al. teaches that plasticizer can be at 0% in the composition, and capsules made with the composition "have a non-animal polymer composition, improved dissolution behavior, an enhanced elasticity and show higher transparency.

Applicants traverse this rejection.

Claim 35 is directed to the homogeneous, thermoreversible gel film of claim 1, wherein the gel film does not contain a plasticizer. In amended claim 1, the alginate is at least one of propylene glycol alginate or salts of said alginate and combinations thereof.

Gilleland was discussed above.

Cade et al. discloses polymer compositions suitable for film forming for hard and soft capsules comprising water soluble cellulose ethers, hydrocolloids and sequestering agents. At column 2, lines 10-29, Cade et al. mentions that suitable hydrocolloids include such items as synthetic gums which are capable of gelling without the addition of alkaline or alkaline earth metal ion. The preferred hydrocolloid is gellan gum, which can be mixed with other materials such as alginates, and various types of gums other than gellan gum. Cade et al. does not disclose the use of propylene glycol alginate.

Claim 35 is not obvious in view of the combined teachings of Gilleland et al. and Cade et al. Neither reference discloses or suggests the use of propylene glycol alginate in thermoreversible gel films, much less thermoreversible gel films that do not contain a plasticizer. As discussed above, the present application explains, for example, at page 7, last paragraph, that certain alginates, such as propylene glycol alginate, are generally considered to be non-gelling. Applicants surprisingly found that propylene glycol alginate provides a homogeneous, thermoreversible gel film having significant strength.

Claim 35 is not obvious over Gilleland et al. in view of Cade et al. Withdrawal of this section 103 rejection is respectfully requested.

**Double Patenting Rejection**

At page 10 of the Office Action, the Examiner rejected claims 1, 2, 8-11, 17, 22 and 35 on the grounds of nonstatutory obviousness-type double patenting as unpatentable over claims 1, 10-15 and 23-25 of copending Application No. 10/824,957.

Applicants request that this rejection be held until such time as notice of patentable subject matter has been received in the applications. Applicants will file an appropriate terminal disclaimer at that time if necessary.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is requested and an early Notice of Allowance is earnestly solicited.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 03-2775, under Order No. 10884-00010-US. A duplicate copy of this paper is enclosed.

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